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MEMORANDUM

CENTRAL FILE

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125D Terbutryn

TO / A: Mr. D.J. Clegg
Head, Pesticides Section
Toxicological Evaluation Division

FROM / DE: Dr. R.M. Sharma

PC 080813

SECURITY CLASSIFICATION - DE SÉCURITÉ:

OUR FILE - NOTRE RÉFÉRENCE:

YOUR FILE - VOTRE RÉFÉRENCE:

DATE: March 20, 1979

SUBJECT / OBJET: Acute oral toxicity of Terbutryne Tech. (GS-14260) in rats

Overall Comment: The audit and validation of this study indicate that despite minor errors and omissions, this study can be considered to be scientifically acceptable.

Acute oral toxicity of Terbutryne Tech. (GS-14260) in rats:

A. Audit:

1. Report no.: IBT A8087 dated January 23, 1970.

2. Date: This study was a combination of 3 range finding studies, each initiated on Dec. 17, 19 and 29, 1969 respectively. The surviving rats were observed for 14 days.

3. Protocol: Not available in the raw data.

4. Test Material: There is no information in the raw data regarding either the shipment or receipt of the test material by IBT with the exception of a work order sheet indicating that the test material was on hand on Dec. 4, 1969.

5. Animal Suitability: The IBT report indicates that rats of Charles River Strain were used. But this can't be verified from the raw data.

6. Raw data: Raw data are available for initial and final body weights, dose/sex/group, reactions observed and mortality/group.

B. Validation & Evaluation:

1. Date: See audit.

2. Protocol: Raw data indicate that 5 rats/sex/group were intubated with the test material as 25% (w/v) aqueous suspension. The body weight of the rats ranged from 181-246 g. The volume of the dose administered ranged from 1.04 to 4.30 ml/rat. The surviving rats were observed for 14 days.

3. Test Material: See audit.

4. Animal Suitability: See audit.

5. Personnel:

Report prepared by: Carmen Mastri
Section Head
Acute Toxicity Dept.

Report approved by: M.L. Keplinger
Manager, Toxicology
&
Otis E. Fancher
Director

Technician: Mabel M. Huck

6. Execution of the study:

a. Body weight: The individual body weight data for day 0 and day 14 as presented in the final IBT report are in agreement with the raw data with the exception of minor errors.

b. Reactions: The data as given in the final report are in agreement with the raw data with the exception of minor errors & omissions. The reaction recorded for each group were as follows:

1.4 g/kg: Hyperactivity and ruffed fur.

2g, 3g, & 4.6/kg: Hyperactivity, diarrhoea, muscular weakness, ruffed fur and emaciation.

c. Mortality: The mortality data as given in the final IBT report are in agreement with the raw data with the exception of minor errors. The results were as follows:

Males: 1/5, 3/5, 4/5 & 5/5 at 1.4, 2.0, 3.0 and 4.6 g/kg respectively.

Females: 0/5, 2/5, 5/5 & 5/5 at 1.4, 2.0, 3.0 and 4.6 g/kg respectively.

d. LD50:

Acute oral LD_{50} for male: 1.9 g/kg
Acute oral LD_{50} for female: 2.1 g/kg

Overall Comment: The audit and validation of this study indicate that despite minor errors and omissions, this study can be considered to be scientifically acceptable.

Review of validation performed by Drs. John A. Stone and James T. Stevens.

We agree with Drs. Stone and Stevens conclusion.

R.M. Sharma

D.J. Clegg

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Chemical:	**Terbutryn (ANSI)**
PC Code:	**080813**
HED File Code	**13000 Tox Reviews**
Memo Date:	**03/20/79**
File ID:	**00000000**
Accession Number:	**412-03-0018**

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